No. 87-1194

IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION,
Petitioner,

v.

PUBLIC CITIZEN, *et al.*,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

MEMORANDUM OF PUBLIC CITIZEN, *ET AL.* IN OPPOSITION

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QUESTION PRESENTED

May the Food and Drug Administration approve color additives that it has concluded are animal carcinogens, on the ground that the risk to humans from their use is "*de minimis*," when the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 376(b)(5), declares that "a color additive . . . shall be deemed unsafe, and shall not be [approved] if it is found . . . to induce cancer when ingested by man or animal"?

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Public Citizen, Nancy Hendree Simpson, Phillip L. Weinberg, and Mary Lou Rooney (hereinafter jointly referred to as "Public Citizen") oppose the petition for a writ of certiorari filed by the Cosmetic, Toiletry and Fragrance Association ("CTFA"), an intervenor in the court below. The unanimous decision of that court rejected the Food and Drug Administration's ("FDA's") recent interpretation of the Federal Food, Drug and Cosmetic Act and reinstated the interpretation that the agency had followed for 25 years. That decision did not create a conflict among the circuit courts of appeals, and, as demonstrated by the Solicitor General's decision not to seek review, this case does not raise an important

public policy issue justifying plenary consideration by this Court.

STATUTE INVOLVED

Section 706(b)(5) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 376(b)(5), provides in pertinent part:

> (B) A color additive . . . (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.

STATEMENT

A. Statutory Framework and Regulatory History

The 1960 Color Additive Amendments, Pub. L. No. 86-618, 74 Stat. 397, *et seq.*, 21 U.S.C. § 376, establish a comprehensive system for regulating the use of color additives in foods, drugs, and cosmetics. Section 376 provides that a color additive is "unsafe" under the FDC Act, and thereby prohibited from sale in interstate commerce, unless the Secretary has "list[ed]" the additive after finding that it is "safe" for its intended use. 21 U.S.C. §§ 376(a), 376(b). In the Amendments, Congress directed the Secretary, who in turn delegated the decision-making authority to the FDA, to take into account a number of factors in deciding whether a dye is safe, including the probable consumption of the dye, its cumulative effect on humans, and "safety factors" which experts agree are "generally recognized as appropriate for the use of animal experimentation data." 21 U.S.C. §§ 376(b)(5)(A)(i),(ii), & (iii). However, in the next paragraph, popularly known as the

"Delaney Clause," Congress adopted a separate rule for color additives that cause cancer. 21 U.S.C. § 376(b)(5)(B). Subsection (ii) of that provision, which is applicable to the dyes at issue in this case, forbids the use of a color additive

> if, after tests which are appropriate for the evaluation of the safety of additives for such use . . ., it is found by the Secretary to induce cancer in man or animal . . ..

21 U.S.C. § 376(b)(5)(B)(ii).

In 1960, when Congress adopted the Color Additive Amendments, there were approximately 200 dyes on the market. Recognizing that all of these color additives could not immediately be tested for safety, Congress created a provisional list, under which the dyes could be marketed until testing on their safety could be completed and the results reviewed by the FDA. Orange No. 17 and Red No. 19, the two additives at issue in this case, were automatically placed on the provisional list in 1960, and since then the FDA has granted approximately 30 extensions to allow additional time for either testing the dyes or evaluating the results of those tests.

In February 1983, the FDA terminated the authorization for the ingested uses of Red No. 19 in drugs and cosmetics on the ground that "the color additive is carcinogenic."[1] In March of that year, Commissioner Arthur Hull Hayes sought approval from the Secretary of Health and Human Services ("HHS") for his decision to remove the remaining, non-ingested uses of Red No. 19 (principally in cosmetics) from the provisional list on the ground that "the Delaney Clause

[1] 48 Fed. Reg. 5262 (February 4, 1983). The CTFA has never challenged this decision, nor did it challenge the decision to terminate the authorization for the ingested uses of Orange No.-17 for the same reason. *See* 48 Fed. Reg.. 13976 (April 1, 1983).

applies." HHS App. 155- 58.[2] That recommendation was subsequently approved by the Assistant Secretary of Health, but HHS Secretary Heckler took no action on it. *Id.*

Approximately one year later, Acting FDA Commissioner Mark Novitch, who had succeeded Commissioner Hayes, submitted another memorandum to the Secretary, recommending that five dyes, including both Red No. 19 and Orange No. 17, be removed from the market on the ground that they are animal carcinogens. This recommendation was also approved by the Assistant Secretary of Health, but was never acted on by the Secretary. *Id.* at 32-41.

On November 26, 1984, and again on December 5, 1984, the current Commissioner, Dr. Frank Young, also recommended that Red No. 19 and Orange No. 17 be removed from the market. *Id.* at 73, 174-77. In his memorandum to the Secretary, Dr. Young explained that he had considered the arguments made by the petitioner CTFA that the risk to humans of the carcinogenic dyes was negligible and had reached his decision to ban the dyes only after "lengthy and difficult analysis of the data and the issues." As Dr. Young explained, there is a

> question [as to] whether a valid risk assessment can be done for an externally applied color additive in the absence of information about the exact chemical composition of the additive, the identity of the carcinogenic component, and the extent of its absorption (as distinct from absorption of the color additive

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[2]Throughout this memorandum, "HHS App. ____" refers to the appendix filed in *Public Citizen v. Dep't of HHS*, No. 86-5150, which the court of appeals decided in the same opinion as this case; "Young App. ____" refers to the appendix filed in the court of appeals in this case; and "Pet. App. ____" refers to the appendix submitted with the petition for a writ of certiorari.

> as a whole). *FDA scientists believe that it is not possible to perform a meaningful risk assessment in that situation.*

Id. at 176 (emphasis supplied). Commissioner Young concluded by stating, "I accept the advice of agency scientists." *Id.*

Nonetheless, the Secretary again did not approve the Commissioner's recommendations. Instead, she directed the agency not to issue any decision on the dyes, and she appointed the Color Additive Scientific Review Panel to determine whether there was sufficient information to conduct a risk assessment on them. *See* Young App. 139. Despite the fact that the FDA had previously concluded that it was not possible to calculate the human risk of Red No. 19 and Orange No. 17, the Panel arrived at a calculation for the human risk from the dyes. On August 7, 1986, relying on the Panel's report, the FDA issued a final rule approving Red No. 19 and Orange No. 17 for non-ingested uses. Pet. App. 35a, 98a.

In its discussion of the final rule, the FDA reaffirmed its finding that Red No. 19 and Orange No. 17 are animal carcinogens. Pet. App. 75a, 140a. It also found that the dyes penetrate the skin, and thus that the animal ingestion studies "are appropriate" for assessing whether cosmetics and other non-ingested products in which the dyes are used pose a risk to humans. Pet. App. 78a, 147a. On this basis, the agency concluded that "the Delaney Clause . . . is applicable." Pet. App. 76a, 141a.

If the FDA had made this finding at any time between the enactment of the Color Additive Amendments in 1960 and 1985, it would have ended its analysis at this point and banned the two additives. Indeed, in its notice approving the dyes, the agency acknowledged that "[a] strictly literal application of the Delaney Clause would prohibit FDA from finding that

[Red No. 19 and Orange No. 17 are] safe and, therefore, prohibit FDA from permanently listing the color[s]." Pet App. 76a, 141a. It even admitted that in the past, "in all likelihood [it] would have terminated the provisional listing" and denied the petition for permanent listing of both dyes. Pet App. 75a, 140a. Nevertheless, the FDA reversed its previous recommendations and approved the two dyes.

Respondents are a national consumer organization and three individuals who use products containing color additives. On August 21, 1986, they filed objections to the FDA's decision to permanently list Red No. 19 and Orange No. 17. Young App. 379-84. In their objections, respondents did not challenge the FDA's estimate of the risks of these dyes, nor did they endorse the agency's findings. Instead, they argued that, as a matter of law, the Delaney Clause prohibited the agency from approving color additives that it has found are animal carcinogens. When the FDA denied those objections, respondents sought review in the United States Court of Appeals for the District of Columbia Circuit.

B. The Court of Appeals Decision

In a unanimous opinion by Judge Stephen Williams, the court of appeals granted the petition. The court was persuaded that the plain meaning of the Delaney Clause prohibited the FDA from approving the color additives. According to the court, "[t]he natural—almost inescapable—reading of this language is that if the Secretary finds the additive to 'induce' cancer in animals, he must deny listing." Pet App. 8a. Since "the agency had made precisely the finding that Orange No. 17 and Red No. 19 'induce[ ] cancer when tested in laboratory animals,' " the court concluded that the Delaney Clause applied. *Id.*

The court then considered the question of whether any exceptions to the plain meaning rule applied. First, it evaluated the *de minimis* doctrine which, it explained, has been used to conserve scarce agency resources. *Id.* at 9a; *Alabama Power Co. v. Costle*, 636 F.2d 323, 360-61 (D.C. Cir. 1979). However, here "application of the doctrine required additional expenditure of agency resources" because of the elaborate process involved in calculating the risk of the dyes. Pet. App. 9a. Therefore, the court concluded, this facet of the *de minimis* doctrine did not justify the agency's departure from the Delaney Clause. *Id.*

The court also responded to the FDA's principal argument that agencies need not follow a statute where "its literal terms lead to 'absurd or futile results.' " *Id.* at 9a, *quoting Alabama Power, supra*, 636 F.2d at 360 n.89, and *United States v. American Trucking Ass'ns*, 310 U.S. 534, 543 (1939). However, the court reasoned that, rather than leading to an absurd result, the plain langauge of the statute would implement the Congressional intent. *Id.* at 11a. Thus, it found two explanations in the legislative history for the absolute rule barring animal carcinogens. Pet. App. 19a-21a. First, in 1960 "Congress, and the nation in general . . ., appear to have been truly alarmed about the risks of cancer." *Id.* at 19a. Second, the court found that "Congress's failure to authorize greater administrative discretion" may have been due to the fact that "it perceived color additives as lacking any great value." Pet. App. at 20a. While the court recognized that "[l]ike all legislative history, this is hardly conclusive," it found that "short of an explicit declaration in the statute barring use of a *de minimis* exception, this is perhaps as strong as [legislation history] is likely to get." *Id.* at 19a.

Judge Williams also addressed the two principal cases that petitioner relied on below, *Monsanto Co. v. Kennedy*, 613 F.2d

947 (D.C. Cir. 1979), and *Scott v. Food and Drug Administration*, 728 F.2d 322 (6th Cir. 1984). He observed that the opinion in *Monsanto* "makes no suggestion . . . that the Delaney Clause . . . was in any way implicated," and that, "[a]s the *Scott* court noted, the FDA's action [there] was completely consistent with the plain language of the statute, as there was no finding that the *dye* [as opposed to one of its constituent parts] caused cancer in animals." Pet. App. at 22a-24a (emphasis in original).

Finally, Judge Williams considered an argument that the FDA made for the first time in its brief in the D.C. Circuit. In the Federal Register notices approving Red No. 19 and Orange No. 17, the agency had concluded that the dyes "induce[ ] cancer when tested in laboratory animals." Pet. App. 75a, 140a. However, on the day that his attorneys filed the agency's brief in the court of appeals, the Commissioner signed a Federal Register "clarification," which the CTFA has never embraced, but which stated that the dyes do not "induce cancer in man or animal within the meaning of the Delaney Clause" because the animal tests were conducted with doses of the dye that are considerably higher than the human exposure. Pet. App. 178a, 184a.

The court disagreed, finding that the "plain language of the Delaney Clause covers all animals exposed to color additives, including laboratory animals exposed to high doses," and that it would have been "surprising if it did not," since "[h]igh-dose exposures are standard testing procedure, today just as in 1960." *Id.* at 28a. Accordingly, Judge Williams rejected this argument as well, and the court granted the petition for review.[3]

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[3]In that same opinion, the court rejected Public Citizen's claim in a related case, *Public Citizen v. Dep't of HHS*, No. 86-5150, that the FDA had violated the law by waiting more than 27 years to decide the safety of

REASONS FOR DENYING THE PETITION

None of the grounds advanced by the CTFA justifies granting the petition. This case is controlled by the plain language of the Delaney Clause which the court below correctly held prohibits the Food and Drug Administration from approving color additives that are animal carcinogens. Congress is certainly entitled to deprive an administrative agency of the discretion to approve carcinogens, and that is precisely what it did in this case. And rather than being "absurd," as CTFA argues, this result is eminently sensible in light of the Congressional concern about cancer, the uncertainty about whether it is possible to identify safe levels of any carcinogen, and the lack of benefits of color additives. Thus, the court below correctly found that a "*de minimis*" exception could not be implied into the Delaney Clause.

In any event, the decision below will not have a sufficient impact to justify review by this Court, and it certainly does not "jeopardize[ ] the food supply," as CTFA claims. Petition at 22. CTFA's fears are more than amply refuted by FDA's earlier recommendation to invoke the Delaney Clause to ban the color additives at issue here, and also by the Solicitor General's decision not to seek review on behalf of the agency.

1. Although CTFA never mentions the language of the statute in the argument portion of its petition, the entire case can and should be resolved by reference to the Delaney Clause. That provision declares that a color additive "shall be deemed unsafe, and shall not be listed . . . if . . . it is found by the Secretary to induce cancer in man or animal." 21 U.S.C.

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several color additives. *See* Pub. Law No. 86-618, 74 Stat. 405, Section 203, *reprinted at* 21 U.S.C.A. § 376 (note). Public Citizen has not sought review of that ruling.

§ 376(b)(5)(B). It is hard to imagine how Congress could have been clearer. It flatly directed the Secretary not to approve any color additive found to induce cancer in animals.

Numerous other authorities have concluded that the FDA does not have the discretion to approve carcinogens subject to the Delaney Clause. Thus, after considering the question in 1979, the Attorney General concluded that "Congress chose to treat potentially carcinogenic substances with extreme caution by enacting the Delaney Clause, which prohibits the Secretary from establishing tolerances for any substance found to induce cancer when ingested by man or animal. Such a substance is therefore unsafe in whatever amount it may be added." 43 Op. Att'y Gen. No. 19 at 17 (1979). Similarly, in 1983, FDA Commissioner Arthur Hull Hayes in a letter to the President of the CTFA, explained that

> [t]he Delaney Clause, as I interpret its history, was intended to be absolute, and FDA has consistently so interpreted the Delaney Clause once it has concluded that the clause is applicable. Under these circumstances, if the Delaney Clause is to be made more flexible, Congress should have the opportunity to make the necessary adjustments.

HHS App. 167.

The casebook co-authored by the lead attorney for the CTFA, which the trade association cites twice in its petition (at 18, 25), also addresses this issue. R. Merrill & P. Hutt, *Food and Drug Law, Cases and Materials* 78 (1980). It explains that the Delaney Clauses, which are virtually identical for both food and color additives, give the FDA the discretion to decide what types of tumors qualify and what tests are appropriate for identifying animal carcinogens. *Id.* at 77-78. But, it concludes,

> the clause affords no flexibility once FDA scientists determine that these conditions are satisfied. *A food additive that has been found in an appropriate test to induce cancer in laboratory animals may not be approved for use in food for any purpose, at any level . . ..*

Id. at 78 (emphasis supplied).

Professor Merrill, who was Chief Counsel of the FDA between 1975 and 1977, has reviewed the issue since the FDA announced its *de minimis* policy and has concluded that the Delaney Clause does not permit the FDA to approve carcinogenic color additives. R. Merrill, Speech, "FDA's 'Erasure' of the Delaney Clause: A Study in Statutory Interpretation" (June 23, 1986), *reprinted in* 50 A. Food & Drug Officials Q. Bull. 199 (1986). Richard Cooper, another former Chief Counsel of the agency, has reached the same conclusion. R. Cooper, "Stretching Delaney Till It Breaks," *Regulation* 11 (Nov/Dec 1985). Finally, the House Committee on Government Operations held hearings on the FDA's reinterpretation of the Delaney Clause and unanimously concluded that "the continued marketing of color additives found by [FDA] scientists to be animal carcinogens violates the Color Additive Amendments to the Food, Drug, and Cosmetic Act." *HHS' Failure to Enforce the Food, Drug, and Cosmetic Act: The Case of Cancer-Causing Color Additives*, H.R. Rep. No. 99-151, 99th Cong., 1st Sess. 20 (1985)(capitalization of quotation changed).

As the court of appeals found, the legislative history confirms that Congress intended to deny the FDA the discretion to approve carcinogenic color additives. That history demonstrates that Congress was told that "a literal interpretation of the Delaney Clause must lead to the prohibition of . . . a substance even though [it appears] in trace amounts" and that it had been asked to give the FDA authority to approve carcinogens where the human risk was low. *Color Additives: Hearings Before the House Committee on Interstate and*

Foreign Commerce, 86th Cong., 2d Sess. 589 (1960) (''*Color Additive Hearings*''); H.R. Rep. No. 1761, 86th Cong., 2d Sess. 13-14 (1960)(''House Report''). Nevertheless, Congress rejected this approach and instead enacted a strict anti-cancer provision. While noting that the Secretary would have full authority to determine in the first instance *whether* a color additive causes cancer in animals, the House Report quoted the Secretary of Health, Education and Welfare, who had played a critical role in drafting the bill, and who emphasized that

> once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen.

House Report at 14.

The House Committee also discussed an industry proposal which would have given the Secretary authority to permit safe tolerances of animal carcinogens, as well as an argument that ''in extraordinary cases, the Secretary . . . should have the authority to decide that a minute amount of a cancer-producing chemical may be added to man's food after a group of scientists consider all the facts and conclude that the quantity to be tolerated is probably without hazard.'' House Report at 13-14. However, on this issue as well, Congress spoke with a clear voice. Thus, the Committee relied on the Secretary's conclusion that an absolute ban on carcinogenic color additives was ''sound public policy in view of the fact'' that scientific techniques do not permit experts ''to state unequivocally how much or how little of a substance that induces cancer when administered to animals will induce cancer when administered to man.'' *Id.* at 14. Again, the Report reiterated that the basis for this judgment was ''grounded on the scientific fact of life that no one, at this time, can tell us how to establish for man a safe tolerance for a cancer-producing agent.'' *Id.*

While the Delaney Clause is rigid, the drafters recognized that in the future there might be a basis for concluding that a color additive is safe for human use, even though it caused cancer in animals. However, rather than drafting the statute to give the FDA the discretion to change the standard in that event, Congress was persuaded by the following reasoning of the Secretary of HEW:

> Whenever a sound scientific basis is developed for the establishment of tolerances for carcinogens, we will request the Congress to give us that authority. We believe, however, that the issue is so important that the elected representatives of the people should have the opportunity of examining the evidence and determining whether or not the authority should be granted.

House Report at 12. Petitioner has chosen not to discuss this crucial piece of legislative history, and yet it undermines the CTFA's central argument that Congress intended to leave the FDA the discretion to approve animal carcinogens.

This point also answers the CTFA's argument, based on the legislative history of the Food Additives Amendment of 1958, that the Delaney Clause was redundant of the general safety standard in the statute. *See* Petition at 15-20. While that may have been an accurate description of how the FDA treated animal carcinogens in 1958, when the agency believed that all carcinogens were *per se* unsafe, Congress included the Delaney Clause to prohibit the FDA from changing the standard in the future, even if it later identified an animal carcinogen that it believed was safe. Indeed, HEW Assistant Secretary Richardson recognized this in the letter on which CTFA relies to support this argument (Petition at 17 & n.22). 104 Cong. Rec. 17415 (1958) ("Any indication that the additive may thus be carcinogenic would, under the terms of the

bill, restrain the Secretary from approving the proposed use of the additive unless and until further testing shows to the point of reasonable certainty that the additive would not produce cancer [in humans and animals].")

2. A literal reading of the Delaney Clause is eminently sensible, and therefore the cases that allow the courts to deviate from a statute where adhering to the plain language would lead to an "absurd" result have no application here. One reason that Congress chose a higher standard for color additives is that, unlike drugs and foods, colors have no medicinal or nutritional value; they only enhance the appearance of the products in which they are used. Congressman Delaney explained how this factor affected the legislation:

> I can say that in the matter of color additives there is every reason why we should have a strong bill. Some food additives serve a useful purpose. They have helped to develop and improve our food supply in many ways.
>
> However, color additives provide no nutrient value. They have no value at all, except so-called eye appeal. We should be particularly careful with them, therefore. They add nothing in any other way.

Color Additive Hearings at 108. *See also Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 162, (1958); *Certified Color Manufacturers Ass'n v. Mathews*, 543 F.2d 284, 296 (D.C. Cir. 1976).

CTFA points out that the Delaney Clause does not apply to many substances, and that in some instances the FDA has the discretion to approve food containing carcinogenic substances (typically in trivial amounts). Petition at 13-14. As we understand it, CTFA's argument is that, since Congress permitted some animal carcinogens in foods, it must have in-

tended to authorize the FDA to permit the sale of carcinogenic color additives as well. However, Congress is entitled to prohibit the sale of carcinogenic color additives that are intentionally added to foods by manufacturers, without adopting the same standard for all food substances. Thus, for example, as CTFA points out (Petition at 23), in the case of aflatoxin in peanuts, Congress gave the FDA the authority to reduce this unavoidable carcinogen to the lowest possible level, but it also recognized that substances such as aflatoxin cannot be eliminated. 21 U.S.C. §§ 342(a), 346. This difference in treatment between unavoidable contaminants and substances that are subject to the Delaney Clause is particularly appropriate because color additives have no significant benefits and because food additives are generally interchangeable. Surely, the CTFA has not demonstrated, as it must to justify a deviation from the plain language of the statute, that this distinction is "irrational" or "absurd."

CTFA also argues that the definition of "food additive" could be stretched to include "virtually all food," including drinking water, which it claims contains "numerous carcinogens." Petition at 25. But this argument ignores the FDA's 30-year history of interpreting the Delaney Clause in the Food Additives Amendment, and the "grandfather clause" in that legislation, which exempts from the Amendment and from the Delaney Clause "any substance used in accordance with a sanction or approval granted," by the FDA or by the Department of Agriculture, prior to 1958. 21 U.S.C. § 321(s)(4). As a result, nothing in the Delaney Clause would lead to condemning food washed in water or to banning the other products identified by the CTFA.

CTFA apparently does not dispute that the Delaney Clause was a sound provision when it was enacted in 1960, or for the 25 years that the FDA refused to license carcinogenic color

additives. Rather, the trade association argues that the provision is "absurd" because in recent years it has become possible to measure the risk of carcinogens and to determine whether the risk is in fact trivial. Petition 24-26. This is, of course, a matter of considerable controversy. As we pointed out above, the FDA scientists did not accept CTFA's argument that it was possible to perform a reliable risk assessment on externally applied color additives. *See* pp. 4-5, *supra*. In fact, Dr. Sanford Miller, Director of the Center for Food Safety and Applied Nutrition, the division of the FDA that had responsibility for evaluating color additives, stated in a memorandum to the Commission that the risk estimates on the dyes could be "hundreds or even thousands of times too low." HHS App. 86. The fact that the FDA's scientists were ultimately overruled by the Secretary of HHS does not detract from the credibility of their scientific opinions, which in turn demonstrate the rationality of the Delaney Clause.

In any event, CTFA has seriously distorted the record to make its argument. Thus, on page 22 of its Petition, the trade association argues that "[m]ost fundamentally, the court [of appeals] ignored FDA's undisputed finding[ ] that 'no one will contract cancer' from exposure to the additives in question." In fact, the full quotation from the agency's Federal Register notice is that "*in all likelihood*, no one will contract cancer as a result of this exposure." Pet. App. 86a, 155a (emphasis indicates portion omitted by CTFA). To make the argument that the FDA concluded that the color additives at issue in this case involve "no additional risk of cancer," petitioner also ignores the concession that the FDA made in the court of appeals that "modern science still cannot guarantee that there is a 'no-effect' level for a carcinogenic color additive," and that "no matter at what level of use *there is always some chance that such an additive will have a carcinogenic effect*." FDA Br. at 21 (emphasis supplied). In other words, the record

demonstrates that the FDA never accepted CTFA's claim that the dyes posed no risk to human health, and thus there is no foundation for CTFA's argument that the plain meaning of the Delaney Clause leads to an absurd result.[4]

3. There is no conflict between the decision below and this Court's decisions in *Permian Basin Area Rate Cases*, 390 U.S. 747, 787 (1968), and *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 410-411 (1914). *See* Petition at 14. In *Permian Basin*, this Court considered whether the Federal Power Commission had the authority to exempt small producers from certain regulatory requirements, where the exemption would "streamline the administrative process" and where "the consequences for consumer prices . . . would be *de minimis*." 390 U.S. at 786. Since the Court found that the exemptions were "fully consistent with the terms and purposes of [the Commission's] statutory responsibilities," *id.* at 787, *Permian Basin* does not stand for the proposition that agencies have inherent authority to create a "*de minimis*" exception to regulatory statutes.

Lexington Mill is even less on point. In that case, this Court evaluated a trial court instruction that had allowed the government to prove a case of adulteration by demonstrating that flour contained a poisonous substance, without proving that the amount of the substance was injurious to health. The provision of the 1906 Food and Drugs Act on which the government had relied provided that a food "shall be deemed to be adulterated . . . if it contain any added poisonous or other added deleterious ingredient *which may render such article injurious to health*. *See* 232 U.S. at 406 (emphasis in original). Follow-

[4]Nor did the court of appeals find that the risks from Red No.19 and Orange No. 17 are "trivial." *See* Petition at 10. The court was not asked to reach and did not decide that issue, and its entire discussion about the significance of various risks included an assumption (but not a finding) that the CTFA's risk estimates were accurate. *See* Pet. App. at 7a.

ing the plain language of the statute, and not any inherent authority that agencies have to depart from statutes, the Court held that the trial court had incorrectly "permitted [the] statute to be read without the final and qualifying words, concerning the effect of the article upon health." *Id.* at 410.

Contrary to CTFA's argument, the decision below also does not conflict with *Scott v. FDA*, *supra*. In *Scott*, the Sixth Circuit upheld the FDA's decision to approve a color additive whose tests did not demonstrate that it caused cancer in animals, even though it contained, in *de minimis* amounts, a carcinogenic constituent. In reaching this decision, the court found that the legislative history of the Color Additive Amendments showed a Congressional intent which "drew a rough, quantitative distinction between a color additive that is deemed unsafe under the Delaney Clause because it causes cancer [as do the colors at issue in this case], and an additive that is not subject to the Delaney Clause because it does not cause cancer even though one of its constituents [when administered alone to animals, in large doses] does." 728 F.2d at 325, *quoting* 47 Fed. Reg. 49628, 49678 (November 2, 1982).

In addition, the decision below will not have a sufficient impact to justify review by this Court. To date, the FDA has attempted to apply the *de minimis* exception to only four color additives, and it has proposed to apply the exception to a single food additive, methylene chloride. *See* 50 Fed. Reg. 51551 (December 18, 1985). The court of appeals simply restored the *status quo* by requiring the agency to adhere to the interpretation of the Delaney Clause that it had followed for the 25 years after the enactment of the Color Additive Amendments. Finally, the Solicitor General, who is far better able than the CTFA to assess the impact of the decision below on the FDA and other federal agencies, has not sought review in this Court.

CONCLUSION

The petition for a writ of certiorari should be denied.

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